K093832

Attachment 3 – 510(k) Summary

510(k) Summary for Levitronix CentriMag Primary Console

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information:

JAN 13 2010

Date Prepared:	December 11, 2009
Submitter's Name & Address:	Levitronix LLC 45 First Avenue Waltham, MA 02451
Contact Person:	Susan K. Hamann Regulatory Affairs Manager Ph: (781) 466-6553 Fax: (781) 622-5090 e-mail: shamann@levitronix.com

B. Device Information:

Trade or Proprietary Name:	Levitronix CentriMag® Primary Console Levitronix CentriMag® Back-Up Console
Common or Usual Name:	Cardiopulmonary Bypass Pump Console
Classification Name:	Class II, DWA, 21 CFR – 870.4380 Control, Pump Speed, Cardiopulmonary Bypass
Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Predicate Devices:

Levitronix CentriMag Primary Console – 510(k) (K083340)
Levitronix CentriMag Back-Up Console – 510(k) (K090004)

D. Device Description

The CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data, system options, and menus. Operator adjustable alarms and parameters are accessible via the system menus.

The CentriMag Back-Up Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data.

E. Intended Use

The Levitronix CentriMag Primary and Back-Up Consoles are indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The Levitronix CentriMag Primary Console has technological characteristics identical to the predicate device.

The Levitronix CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data.

The CentriMag Primary Console uses single phase AC power and is capable of a flow rate of up to 9.9 LPM. Each Primary Console contains a

rechargeable internal battery that is capable of maintaining Primary Console functionality in the event of a loss of AC Power.

The Levitronix CentriMag Back-Up Console has technological characteristics identical to the predicate device.

The CentriMag Back-Up Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data.

Identical to the predicate device, the Back-Up Console uses single phase AC power and is capable of controlling the Motor and Pump to produce a flow rate of up to 9.9 LPM at maximum pressure head of 600 mmHg when used with the CentriMag Blood Pump. In addition each Back-Up Console contains a non-rechargeable, field replaceable internal battery that is capable of powering the Back-Up Console in the event of a loss of AC Power.

G. Comparison to Predicate Device

The Levitronix CentriMag Primary and Back-Up Consoles have indications for use which are substantially equivalent to the predicate devices, are composed of the same or equivalent materials as the predicate devices, have equivalent design features as the predicate devices, and have functional characteristics which are the same or equivalent to those of the predicate devices. Due to the equivalency of indications for use, materials of composition, design features, and functional characteristics, the devices raises no new safety or effectiveness issues.

H. Summary of Performance Data

The proposed labeling change did not require any performance characteristics testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 13 2010

Levitronix LLC
c/o Ms. Susan K. Hamann
45 First Avenue
Waltham, MA 02451

Re: K093832
Trade/Device Name: CentriMag Primary Console and Back-Up Console
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: II
Product Code: DWA
Dated: December 11, 2009
Received: December 14, 2009

Dear Ms. Hamann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1 – Indications for Use Statement

Applicant: **Levitronix LLC**

510(k) Number (if known): K093832

Device Name: **CentriMag® Primary and Back-Up Consoles**

Indications for Use:

The Levitronix CentriMag Primary and Back-Up Consoles are indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedmen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093832